

REMARKS

Claims 21-38, 40-46, 48-54, 56, 57 and 63 remain rejected as unpatentable over U.S. Patent No. 5,858,410 ("Muller") and U.S. Patent No. 5,739,152 ("Andersson"). The rejection is traversed to the extent it is applied to the claims as amended.

Claims 21, 22, and 38, from which depend the remaining claims subject to the rejection, have been amended to specify that the recited compositions are "autoclaved" compositions. There is no suggestion in the cited references of compositions that are resistant to the size altering effects of autoclaving.

Applicants note the Examiner's assertion on page 2 of the Office Action that the prior art teaches the use of trehalose in combination with a water insoluble drug and phospholipid surface modifier. Applicants respectfully point out that the instant invention is based not on the use of trehalose as such but on the insight that these can be combined in such a way so as to make a composition resistant to the size-altering effects of steam sterilization. That is, the cited art lacks any suggestion of the currently claimed autoclaved (emphasis added) composition.

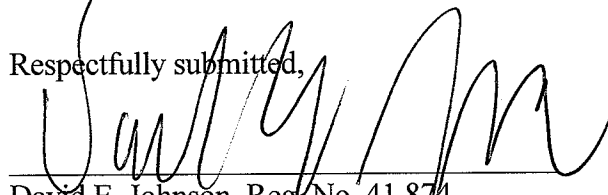
Muller lacks any teaching or suggestion that a thermoprotecting agent confers resistance to particle size increase following autoclaving, or of a procedure for autoclaving compositions without increasing their size. Andersson does not cure the deficiencies of Muller as Andersson is also silent about the protective effect of a thermoprotecting agent now required by the claims. Muller is likewise silent regarding a weighted mean particle size increase of not more than two-fold during and after steam sterilization as discovered and presently claimed by Applicants. Andersson does not contemplate suspensions comprising particles having a weighted mean particle size that does not increase more than two-fold during and after terminal steam

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sterilization. In short, there is no suggestion in the combination of references of an autoclaved composition required by the claims. Accordingly, claims 21-38, 40-46, 48-54, 56, 57 and 63-66 are non-obvious over the combination of Muller and Andersson. Applicants request reconsideration and withdrawal of the rejection.

Applicants submit that the application is in condition for allowance and request an action for same. A petition for an extension of time and Notice of Appeal accompany this response. Please charge any additional fees due, or credit any overpayment of same, to Deposit Account 50-0311, Attorney Reference No.: 28069-503001US.

Respectfully submitted,



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Date: July 19, 2010